K070984

Abbott Diabetes Care

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502
t: (510) 749-5400

NOV - 1 2007

510(k) Summary

(as required by 21 CFR 807.92)

Date Prepared:	October 09, 2007
Company	Abbott Laboratories
Division	Abbott Diabetes Care Inc.
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Telephone No.	510-749-5400
Fax No.	510-864-4791
Contact Person:	Maria Trejo Regulatory Affairs Associate Tel No. 510-749-6384 Fax No. 510-864-4791 maria.trejo@abbott.com
Device Name:	Precision® Point of Care Blood Glucose Test Strip Optium® Point of Care Blood Glucose Test Strip
Common Name:	Blood Glucose Test Strip
Classification Name:	Glucose Dehydrogenase, Glucose. Glucose Test System, Class II (21 CFR §862.1345, Product code LFR)
Predicate Device:	Precision®/ Optium® Point of Care Blood Glucose Test Strips (K021960)

Description of the Device:

The Precision® /Optium® Point of Care Blood Glucose Test Strips work on the principle of amperometric biosensor technology, by determination of glucose oxidised by the enzyme (Glucose Dehydrogenase, GDH) catalysed reaction with Nicotinamide Adenine Dinucleotide (NAD). The reduced form of NAD (NADH) is re-oxidized by reaction with the electrochemical mediator, 1,10 phenanthroline quinone (1,10PQ). The reduced mediator is re-oxidized via electron transfer at the electrode surface. This current is translated into a number by the meter, after applying lot specific information from the supplied ROM calibrator and after a 20 second countdown, a concentration value is presented to the user.

Abbott
Diabetes Care

Intended Use:

The Precision®/Optium® Point of Care Blood Glucose Test Strips quantitatively measure glucose (D-glucose) in fresh neonatal, venous, arterial and fingertip capillary whole blood. The test strips are for use outside the body (*in vitro* diagnostic use) by healthcare professionals for use in healthcare facilities with either the Precision Xtra® or Optium® Blood Glucose Monitoring Systems. Home users may use the system for capillary samples only. The test strips are not for use in diagnosis or screening of diabetes mellitus, but are to be used as an aid in monitoring the effectiveness of diabetes control programs.

Summary of Technological Characteristics:

The Precision® Point of Care Blood Glucose Test Strips/ Optium® Point of Care Blood Glucose Test Strips have the same fundamental scientific technology and the same intended use as the current Precision® Point of Care Blood Glucose Test Strips and Optium® Point of Care Blood Glucose Test Strips which is based on amperometric biosensor technology. The Precision® Point of Care Blood Glucose Test Strips/ Optium® Point of Care Blood Glucose Test Strips are substantially equivalent to the current predicate device.

Assessment of Non-Clinical Performance Data:

The performance of the Precision®/Optium® Point of Care Blood Glucose Test Strips was verified through non clinical testing in the laboratory. These studies demonstrated that the Precision® Point of Care Blood Glucose Test Strips/ Optium® Point of Care Blood Glucose Test Strips are substantially equivalent to the current Precision® Point of Care Blood Glucose Test Strips/Optium® Point of Care Blood Glucose Test Strips for blood glucose measurements and are suitable for its intended use.

Assessment of Clinical Performance Data:

The performance of the Precision®/Optium® Point of Care Blood Glucose Test Strips was also verified through clinical testing. Some of the test performed and passed were altitude, dynamic range, precision , linearity, accuracy, interference, oxygen sensitivity, environmental, hematocrit, shipping and shelf life. These studies demonstrated that the Precision® Point of Care Blood Glucose Test Strips/ Optium® Point of Care Blood Glucose Test Strips are substantially equivalent to the current Precision® Point of Care Blood Glucose Test Strips/Optium® Point of Care Blood Glucose Test Strips for blood glucose measurements and are suitable for its intended use.

Conclusion:

Results of clinical and non-clinical testing demonstrate that the performance of the Precision® Point of Care Blood Glucose Test Strips and Optium® Point of Care Blood Glucose Test Strips, when used according to the intended use stated above, are acceptable and comparable to the performance of the previously mentioned predicate device for blood glucose testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Abbott Laboratories
Abbott Diabetes Care Inc.
c/o Ms. Maria Trejo
Regulatory Affairs Associate
1360 South Loop Road
Alameda, CA 94502

NOV - 1 2007

Re: k070984
Trade/Device Name: Precision® Point of Care Blood Glucose Test Strips
Optium® Point of Care Blood Glucose Test Strips
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System.
Regulatory Class: Class II
Product Code: LFR, NBW
Dated: October 10, 2007
Received: October 15, 2007

Dear Ms. Trejo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070984

Device Name: Precision® Point of Care Blood Glucose Test Strips
Optium® Point of Care Blood Glucose Test Strips

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

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ision Sign-Off

ffice of In Vitro Diagnostic Device
valuation and Safety

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